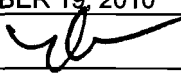


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PTO/SB/33 (01-09)

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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) 1001.1632101	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>NOVEMBER 19, 2010</u> Signature  Typed or printed name <u>THU H. LE-TO</u>	Application Number 10/725,890		Filed DECEMBER 2, 2003
	First Named Inventor STEVEN E. WALAK		
	Art Unit 3767	Examiner BRADLEY J. OSINSKI	

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

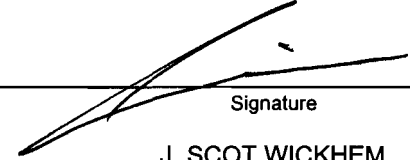
This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)
- ☒ attorney or agent of record.  
Registration number 41376
- ☐ attorney or agent acting under 37 CFR 1.34.  
Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

  
Signature  
J. SCOT WICKHEM  
Typed or printed name  
612.677.9050  
Telephone number  
11/19/2010  
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  
Submit multiple forms if more than one signature is required, see below\*.

☐ \*Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**P A T E N T**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**


Applicant:	STEVEN E. WALAK	Confirmation No.:	3380
Serial No.:	10/725,890	Examiner:	Bradley J. Osinski
Filing Date:	DECEMBER 2, 2003	Group Art Unit:	3767
Docket No.:	1001.1632101	Customer No.:	11050
Title:	COMPOSITE MEDICAL DEVICE AND METHOD OF FORMING		

**PRE-APPEAL CONFERENCE BRIEF**

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\_\_\_\_\_  
Thu H. Le-To

\_\_\_\_\_  
NOVEMBER 19, 2010  
Date

Dear Sir:

In response to the Final Office Action of September 22, 2010, Appellants hereby request a Pre-Appeal Conference and file this Pre-Appeal Conference Brief concurrently with a Notice of Appeal. Appellants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

Claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, 73, 76, and 77 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ren et al., U.S. Patent No. 6,045,547 (hereinafter "Ren"), in view of Viera, U.S. Patent No. 6,039,699. Appellants respectfully traverse this rejection.

Independent claim 1 requires, in part, constructing a metallic composite elongate shaft by co-drawing or co-extruding a metallic outer portion about a metallic inner portion including a lumen therein, wherein co-drawing or co-extruding the metallic outer portion

about the metallic inner portion forms the composite elongate shaft as a unitary construction. Independent claims 57 and 73 each require, in part, a first metallic material co-drawn or co-extruded about a second metallic material, the materials being formed together as one unitary construction in claim 57, and forming a unitary metallic composite elongate shaft in claim 73.

The Examiner asserts that Ren teaches a co-extruded polymer catheter. The Examiner also acknowledges that Ren does not teach that the inner portion and the outer portion are both made from metallic materials. Accordingly, Ren cannot teach co-extruding or co-drawing metallic materials to form a metallic composite shaft having a lumen therein, as required by the claims. The Examiner asserts that “Viera teaches a multi-layer guidewire where each the inner and outer layers are made of metal” [sic]. Appellants note that the guidewire of Viera does not include a lumen defined in the metallic inner portion, as required by the claims. Furthermore, the guidewire of Viera does not appear to be formed as a unitary construction by co-extrusion or co-drawing, as required by the claims. Instead, Viera appears to teach a multi-layer guidewire produced by one of a plurality of assembly methods (see column 4, lines 26-29) that appear to expressly discount constructing a unitary metallic composite shaft by co-drawing or co-extruding. Furthermore, Viera does not appear to disclose, expressly or inherently, that the individual metallic components (which are assembled together to form the multi-layer guidewire) are extruded or drawn. Accordingly, Viera does not appear to disclose the metal processing techniques claimed. Ren also fails to teach the claimed metal processing techniques. Therefore, the cited references, taken alone or in combination, fail to teach all of the elements of independent claims 1, 57, and 73.

The Examiner cites MPEP 2113 in rejecting independent claim 1. Appellants acknowledge that claim 1 is indeed a product by process claim, and that “determination of patentability is based on the product itself”. The Examiner asserts that the combination of Ren and Viera renders the product of claim 1 obvious. More specifically, the Examiner asserts that it would be obvious to “make a catheter of Ren et al using the materials suggested by Viera, in this case metallic inner and outer layers”. Appellants respectfully disagree, as the cited combination fails to teach all of the structural characteristics required by the claims, and furthermore, the proposed modification appears to be improper.

As discussed in the response dated March 25, 2010, there are differences in the process for extruding polymers and metals. While using the same term, the actual process of extruding of a polymer is done differently and results in different structural properties than extruding a metal, as would be understood by one of ordinary skill in the art. One of ordinary skill in the art will recognize that the physical structure of an extruded polymer and an extruded metal are implicitly different. Accordingly, the process and resulting characteristics of extruding a polymer (as taught by Ren) do not apply equally to extruding a metal (which is not taught by either reference), and the metallic materials of Viera cannot simply be substituted into Ren's process of extruding polymers.

The Examiner appears to contend that the differences are irrelevant to patentability of the claims. Appellants disagree, and respectfully point out that cited MPEP 2113 also states:

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

Appellants submit that the Examiner appears to have improperly failed to consider the distinctive structural characteristics imparted upon the metallic materials by the co-extruding or co-drawing process required in the independent claims. One of ordinary skill in the art will recognize that extruded metal possesses a different physical structure than, for example, machined, cast, or rolled metal. When extruded, the solid metallic material "flows" longitudinally, and the grains are re-arranged into an elongated structure. The flow pattern influences the quality and mechanical properties of the finished product. Improper metal flow can produce various defects such as surface cracking or tearing, pipe, and internal cracking. Therefore, the extrusion process affects the structural characteristics of the material in a way that is best described by the process itself, similar to, for example, the heat treating process of annealing. While a detailed metallurgical description of the effects of the process exists, one of ordinary skill in the art does not require such a description to understand the structural characteristics produced by the process. Accordingly, the claim limitations "co-extruding or

co-drawing” must be given patentable consideration. Neither Ren nor Viera discloses co-extruding or co-drawing metallic materials (and more specifically, multiple layers of metallic materials, as required by the claims), or the physical, structural changes that result therefrom.

In the Response to Arguments, “the Examiner takes the position that a product formed by co-extruding the layers together is taught by Ren and Viera suggests specific alternative materials such as metals.” However, substitution of the non-extruded metallic materials of Viera into the polymer extrusion process of Ren appears to be improper. Ren does not appear to teach metal processing techniques. While Viera does appear to teach a metal guidewire, Viera does not appear to teach, expressly or inherently, that the guidewire materials are co-extruded or co-drawn. Additionally, neither reference appears to teach, expressly or inherently, metallic component layers that are extruded or drawn, such that they would possess the same structural characteristics as those of the claimed device.

For at least the reasons discussed above, the cited references do not appear to properly teach or suggest all of the elements of independent claims 1, 57, and 73, as is required to establish a *prima facie* rejection. Accordingly, claims 1, 57, and 73 are believed to be patentable over the cited references. Since claims 2--9, 11, 13, 15, 16, 18-21, 25-26, 59, 61, 63-64, 66-68, 76, and 77 depend therefrom claims and add additional elements, these claims are submitted to be in condition for allowance as well. Appellants respectfully request that the rejection be withdrawn.

Claims 12, 17, 60 and 65 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ren and Viera as applied to claims 1 and 57 above, and further in view of O’Brien et al., WO 99/58184. Claims 14 and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ren and Viera as applied to claims 1 and 57 above, and further in view of Rooney, U.S. Patent 6,306,105.

As discussed above, independent claims 1 and 57 are believed to be patentable over Ren and Viera. O’Brien et al. and Rooney do not appear to remedy the shortcomings of Ren and Viera with respect to claim 1 and 57. Therefore, claims 1 and 57 are believed to be patentable over the cited combinations. Since claims 12, 14, 17, 60, 62, and 65 depend therefrom and add additional elements, Appellants submit that these claims are also patentable over the cited references. Withdrawal of the rejections is respectfully requested.

Claims 74, 75, and 78 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ren and Viera as applied to claim 1 above, and further in view of Jones et al., U.S. Patent 5,843,050. Appellants respectfully traverse the rejection.

Independent claims 74 and 75 each require, in part, a first metallic material co-drawn or co-extruded about a second metallic material, the materials being formed together as one unitary construction in claim 74, and forming a unitary metallic composite elongate shaft in claim 75. As discussed above with respect to claim 1, Ren and Viera, alone or in combination, do not appear to teach co-drawing or co-extruding a metallic material.

Therefore, the cited references do not appear to teach or suggest all of the elements of independent claims 74 and 75, as is required to establish a *prima facie* rejection. Jones et al. do not appear to remedy the shortcomings of Ren and Viera with respect to independent claims 1, 74, and 75. Accordingly, claims 1, 74, and 75 are believed to be patentable over the cited references. Since claim 78 depends from claim 1 and adds additional elements, claim 78 is also believed to be patentable over the cited references. Withdrawal of the rejection is respectfully requested.

In view of the foregoing, all pending claims are believed to be in condition for allowance. Reconsideration and withdrawal of the rejections are respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

STEVEN E. WALAK

By his Attorney,

Date: 11/19/2010

  
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